TOOLS FOR INSERTIONAL MUTAGENESIS IN THE MOUSE

Release Date: January 25, 2001

RFA: RFA-DA-01-011

National Institute on Drug Abuse
(http://www.nida.nih.gov)
National Institute on Aging
(http://www.nih.gov/nia/)
National Institute of Mental Health
(http://www.nimh.nih.gov)
National Institute of Dental and Craniofacial Research
(http://www.nidcr.nih.gov)
National Eye Institute
(http://www.nei.nih.gov)
National Institute on Deafness and Other Communication Disorders
(http://www.nidcd.nih.gov)
National Human Genome Research Institute
(http://www.nhgri.nih.gov)
National Institute of Diabetes and Digestive and Kidney Diseases
(http://www.niddk.nih.gov)
National Institute of Arthritis and Musculoskeletal and Skin Diseases
(http://www.nih.gov/niams)
National Institute of Allergy and Infectious Diseases
(http://www.niaid.nih.gov)
National Institute of Neurological Disorders and Stroke
(http://www.ninds.nih.gov)

Letter of Intent Receipt Date: March 11, 2001
Application Receipt Date: April 11, 2001

THIS REQUEST FOR APPLICATIONS (RFA) USES THE “MODULAR GRANT” AND “JUST-IN-TIME” CONCEPTS. IT INCLUDES DETAILED MODIFICATIONS TO STANDARD PPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING APPLICATIONS IN RESPONSE TO THIS RFA.

PURPOSE

This RFA solicits proposals for development of tools and techniques for the establishment of random and targeted sequence-tagged insertion libraries of embryonic stem (ES) cells that can be used to generate mutant mice in which the expression of the tagged gene could be controlled temporally and spatially. The development of such a resource for wide distribution to the scientific community would make it possible to scan the sequence database for any gene of interest and order the corresponding targeted ES cell line. Ideally, the insertional mutagenesis system developed would permit a wide range of genetic analyses and manipulations, including enhancer-trapping, conditional knockouts, conditional expression or overexpression, etc. It also would permit the larger community of investigators to utilize genomic resources efficiently.

This effort complements ongoing National Institutes of Health (NIH) efforts to create and characterize induced point mutations in mice using ethylnitrosourea (ENU) and provides a functional genomics tool to translate the information from the Mouse Genome Sequencing Project. Further information about NIH initiatives on mouse genomics and genetics resources is available at http://www.nih.gov/science/mouse.

This initiative will utilize the research project grant (R01) and exploratory/development grant (R21) mechanisms. It will be run in parallel with a program of identical scientific scope that uses the Small Business Innovation Research/Small Business Technology Transfer Research (SBIR/STTR) programs (http://grants.nih.gov/grants/funding/sbirsttr1/index.pdf).

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA, "Tools for Insertional Mutagenesis in the Mouse," is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople/.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

MECHANISM OF SUPPORT

This RFA will use the NIH research project grant (R01) and exploratory/developmental grant (R21). Applicants are advised to contact the appropriate Institute program staff listed under INQUIRIES for additional information and specific application procedures.

For research in methods development, the R21 mechanism is particularly appropriate. The R21 mechanism is intended to encourage exploratory research projects with sound methodology and strong rationales in underdeveloped research areas, such as those covered in this RFA. All applicants must use the NIDA R21 Guideline at http://grants.nih.gov/grants/guide/pa-files/PA-01-012.html. The R21 is limited to $100,000 maximum direct costs per year for up to three years. Investigators may also choose to include methods development as one component within the R01 mechanism.

Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for an application submitted in response to this RFA may not exceed three years. This RFA is a one-time solicitation. Future new or competing continuation applications will compete with all investigator-initiated applications and be referred and reviewed according to the customary peer review procedures.

This RFA is the result of a trans-NIH initiative, and awards will be made through the institute whose mission is most closely related to the proposed work. The earliest anticipated award date is September 30, 2001.

FUNDS AVAILABLE

The participating institutes intend to commit approximately $2.8 million in total costs [direct plus Facilities and Administrative (F & A) costs] in FY 2001 to fund six to eight new grants in response to this RFA. An applicant may request a project period of up to three years. For R01 grants, an applicant may request a budget for direct costs of up to $250,000 per year, including F & A costs on consortium arrangements. For an exploratory/development grant (R21), an applicant may request a budget for direct costs of up to $100,000 per year, including F & A costs on consortium arrangements. Because the nature and scope of the research proposed may vary, it is anticipated that the size of awards also will vary. Although the financial plans of the participating institutes provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

RESEARCH OBJECTIVES

Background

The use of transposon tagging and retroviral insertional mutagenesis in model organisms such as Drosophila, C. elegans, and zebrafish has greatly facilitated the characterization of gene function and permitted rapid cloning of the mutated gene. This approach has complemented analysis of gene function using chemically and X-ray-induced mutations where great effort is expended in positional cloning of the mutant gene. Insertional mutagenesis in mice is made practical by the availability of efficient methods of transfecting ES cells, the production of a 2.5 to 3.5X draft of the mouse genome using C57BL/6 mouse strain by February 2001, polymerase chain reaction (PCR), and automated sequencing methods.

The development of both random and targeted sequence-tagged insertion libraries in mouse ES cells would greatly facilitate analysis of gene function in mice and permit the rapid development of mouse models for human genetic disease. Not only would such an approach create an induced mutation resource, but it would also permit analysis of patterns of gene expression. The value of this resource would be greatly enhanced by the use of site-specific gene recombination systems or trans-acting factor binding sites that would allow the expression of the tagged gene to be controlled temporally and spatially.

There are two recombination systems currently used to create conditional mutations or knockouts in mice are the cre-lox and FLP-FRT site-specific recombination systems. The usefulness of these recombination systems in vertebrate systems is dependent on the activity of the recombinase and the ability to drive the expression of the recombinase with non-mammalian promoters, such as ecdysone or tetracycline sensitive promoters. The ability to control the spatial expressions of the recombinase is limited by the lack of well-characterized enhancers that control gene expression. To overcome these obstacles, modifications of these recombinase systems, as well as the development of new ones, are needed. In addition, the flexibility of existing systems can be enhanced through the use of inducible promoters or fusion protein recombinases that are activated by ligands such as steroids.

The creation of appropriate insertional mutagenesis vectors containing site-specific recombination targets will also aid in the generation of chromosomal deletions, duplications, and inversions when another genetic locus is tagged with a vector containing the same target sequence. Chromosomal aberrations are an important tool for selecting and mapping mutations in a specific chromosomal region and for positional cloning, as well as for the study of position effects and

contiguous gene syndromes. In addition, inversions can be combined to produce balancer chromosomes. Balancer chromosomes carrying dominant phenotypic markers simplify the maintenance of recessive mutations and combinations of alleles from generation to generation because the balancer prevents recombination. Balancer chromosomes also facilitate isolation and high-throughput screening for new recessive mutations.

Current estimates are that a total of 500,000 ES cell lines may be needed to tag every single mouse gene. Thus high-throughput methods are needed to automate the processing of large numbers of clones and to identify the site of insertion.

The use of C57BL/6 ES cells will speed the distribution of mice in a defined isogenic background by eliminating the need to cross sv129 mice over successive generations into C57BL/6. Many of the current sv129 cell lines in use are derived from different strains of sv129 mice, making comparisons among the various targeted mutations difficult until transferred to a defined genetic background. Moreover, much of the public chemical mutagenesis and sequencing effort is being done in C57BL/6. Thus, crosses between mutations created by ENU in C57BL/6 and C57BL/6 carrying a targeted deletion can be performed in a single generation without concern about the effects of genetic background.

It is anticipated that the results of funded research projects will eventually lead to production of new complete libraries of ES cells with random or targeted insertional mutations for wide distribution to the research community.

Examples of research that may be considered responsive to this RFA include, but are not limited to, those listed below.

o Feasibility studies for the establishment of sequence-tagged insertional libraries of C57BL/6 ES cells in which the expression of the tagged gene can be controlled temporally and spatially.

o The development of new or modified site-specific recombination systems for efficient random and targeted insertional mutagenesis and enhanced control of conditional expression.

o The development of novel vectors that allow imaging of specific cell types or tissues, metabolic activity, or other cellular or physiological functions.

o The invention of efficient systems for transposon tagging in mammalian systems for the wide use of the scientific community.

o The development of vectors for identification ("trapping") of promoters and enhancers that could be used for tissue-specific and temporal expression of recombinases and for the study of gene expression patterns.

o Methods to automate the processing of large numbers of clones and to identify the sites of insertion.

SPECIAL REQUIREMENTS

Restricted availability of unique research resources upon which further studies are dependent can impede the advancement of research and delivery of medical care. The sharing of biomaterials, data, and software in a timely manner, on the other hand, has been an essential element in the rapid progress that has been made in the genetic analysis of mammalian genomes. NIH policy requires investigators to make unique research resources readily available for research purposes to qualified individuals within the scientific community when they have been published [NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps); Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, December 1999 (http://www.nih.gov/od/ott/RTguide_final.htm)]. Biomaterials and other patentable research resources (e.g., mutagenesis protocols, vectors, embryonic cell lines, etc.) produced in projects funded by this RFA are expected to be made available and distributed to the broader scientific community.

The NIH is interested in ensuring that the research resources developed through this RFA become readily available to the research community for further research, development, and application, in the expectation that this will lead to products and knowledge of benefit to the public. For this reason, NIH is concerned that patents on the vectors, mutagenesis methods, cell lines, and other research resources might have a chilling effect on the future development of products and information that may improve the public health. At the same time, NIH recognizes the rights of grantees to elect and retain title to subject inventions developed under federal funding under the provision of the Bayh-Dole Act.

There are two special requirements for this RFA regarding research resources produced in proposed projects:

(1) Applicants are required to include in their application a specific plan by which they will share research resources with the wider scientific community.

(2) Applicants are required to include a plan addressing if, or how, they will exercise their intellectual property rights while making available to the broader scientific community patentable research resources. These plans should be consistent with the policies of their institutional offices of technology transfer.

Applicants are encouraged to discuss their proposed plans for addressing these requirements with their institutional offices of technology transfer. Each of the two requirements is discussed in detail below.

Plan to Share Research Resources

To address the joint interests of the government in the availability of, and access to, the results of publicly funded research, NIH requires applicants who respond to this RFA to propose detailed plans for sharing the research resources generated through the grant. It is expected that the resources to be shared include all materials developed in projects funded under the RFA, including but not limited to, the following: vectors, high-throughput methods for identifying insertion sites, mutagenesis protocols, and cell lines. A reasonable time frame for release of materials should be specified in the application and will be considered during the review of the plan for sharing.

It is expected that the investigator's data and biomaterials sharing plan will include the access to biomaterials and methods not currently available to the wider scientific community.

The scientific review group will evaluate the adequacy of the proposed plan for sharing and data access. Comments on the plan and any concerns will be presented in an administrative note in the Summary Statement. The adequacy of the plan will be considered by NIH program staff and will be important in determining whether the grant shall be awarded. The sharing plan as approved, after negotiation with the applicant when necessary, will be a condition of the award. Evaluation of non-competing continuation applications will include assessment of the effectiveness of research resource release.

Intellectual Property Rights

NIH is interested in ensuring that the research resources developed through this RFA become readily available to the research community.

With regard to patentable research results, such as mutagenesis protocols, methodologies, cell lines, and vectors, the NIH requires applicants who respond to this RFA to develop a plan addressing if, or how, they will exercise their intellectual property rights while making available to the broader scientific community research resources produced in projects funded under this RFA. This is expected to include an elaboration of the applicant's anticipated plans to generate, or not generate, patents and/or exclusive or non-exclusive licensing of biomaterials and other patentable subject matter created in projects funded under this RFA. This plan should be consistent with the applicant's institution's policies on intellectual property rights.
This plan is also expected to include disclosure of any pre-existing agreements involving intellectual property rights, including options to for-profit research sponsors that are associated with biomaterials and data that may be generated. The requirement for this plan is in addition to the requirement for the plan for sharing and disseminating research resources described in the previous section.

The majority of transfers to not-for-profit entities should be implemented under terms no more restrictive than the Uniform Biological Materials Transfer Agreement (UBMTA). In particular, recipients are expected to use the Simple Letter Agreement provided at http://www.nih.gov/od/ott/RTguide_final.htm, or another document with no more restrictive terms, to readily transfer unpatented tools developed with NIH funds to other recipients for use in NIH-funded projects. If the materials are patented or licensed to an exclusive provider, other arrangements may be used, but commercialization option rights, royalty reach-through, or product reach-through rights back to the provider are inappropriate.

Similarly, when for-profit entities are seeking access to NIH-funded tools for internal use purposes, recipients should ensure that the tools are transferred with the fewest encumbrances possible. The Simple Letter Agreement may be expanded for use in transferring tools to for-profit entities, or simple internal use license agreements with execution or annual use fees may be appropriate.

The scientific review group will evaluate the adequacy of the proposed plan for handling intellectual property rights. Comments on the plan and any concerns will be presented in an administrative note in the Summary Statement. The adequacy of the proposed plan will be considered by NIH program staff in determining whether the grant shall be awarded. The plan as approved, after negotiation with the applicant when necessary, will be a condition of the award.

Evaluation of non-competing continuation applications will include assessment of the awardee's adherence to the proposed plan.

Applicants also are reminded that the grantee institution is required to disclose each subject invention to NIH within two months after the inventor discloses it in writing to grantee institutional personnel responsible for patent matters. The awarding institute reserves the right to monitor awardee activity in this area to ascertain if patents or patent applications on mutagenesis protocols, cell lines, vectors, or other patentable subject matter are adversely affecting the goals of this RFA.

Principles and guidelines for recipients of NIH research grants on obtaining and disseminating biomedical research resources can be found at http://www.nih.gov/od/ott/RTguide_final.htm.

Post-Award Management

During the course of the award period, the Principal Investigator may be invited to meet with NIH staff to review and share scientific progress. Other scientists external to and knowledgeable about these studies also may be invited to participate. Application budget requests should include travel funds for the Principal Investigator to attend annual meetings in the metropolitan Washington, D.C., area.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes a descriptive title of the overall proposed research; the name, address and phone number of the Principal Investigator; and the number and title of this RFA. In addition, the letter of intent should identify all other personnel who will be involved in the research and their institutions. Although the letter of intent is not required, is not binding, does not commit the sender to submit an application, and does not

enter into the review of subsequent applications, the information that it contains allows NIH staff to estimate the potential review workload and to plan for the review.

The letter of intent is to be sent to:

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Division of Neuroscience and Behavioral Research
National Institute on Drug Abuse/NIH
6001 Executive Boulevard, Room 4284, MSC 9555
Bethesda, MD 20892-9555
Phone: (301) 443-6300
Fax: (301) 594-6043

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants. Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, Phone (301) 435-0714, E-mail: GrantsInfo@nih.gov.

SPECIFIC APPLICATION INSTRUCTIONS FOR MODULAR GRANTS

The modular grant concept establishes specific modules in which direct costs may be requested, as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers, and institute staff. The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants, with the modifications noted below.

BUDGET INSTRUCTIONS

Modular Grant applications will request direct costs in $25,000 modules, up to a total direct cost request of $250,000 per year. The total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below:

PHS 398

o FACE PAGE - Items 7a and 7b should be completed, indicating Direct Costs (in $25,000 increments up to a maximum of $250,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the initial budget period. Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.

o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

o NARRATIVE BUDGET JUSTIFICATION - Prepare a Modular Grant Budget Narrative page. (See http://grants.nih.gov/grants/funding/modular/modular.htm for sample pages.) At the top of the page, enter the total Direct Costs requested for each year. This is not a Form page.

Under Personnel, list all project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided. However, the applicant should use the NIH appropriation language salary cap and the NIH policy for graduate student compensation in developing the budget request.

For Consortium/Contractual costs, provide an estimate of total costs (Direct plus F&A) for each year, each rounded to the nearest $1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of all personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested Modular Direct Cost amount. Include the letter of intent to establish a consortium.

Provide an additional narrative budget justification for any variation in the number of modules requested.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is

required for all all personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at: http://grants.nih.gov/grants/funding/modular/modular.htm

- Complete the educational block at the top of the Form page;
- List position(s) and any honors;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years; and
- List selected peer-reviewed publications with full citations.

o CHECKLIST - This page should be completed and submitted with the application. If the F&A rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs for the initial budget period and all future budget years.

The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

The RFA label available in the PHS 398 (rev. 4/98) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the title and number of this RFA must be typed in Item 2 on the face page of the application form, and the YES box must be marked. The sample RFA label available at: http://grants.nih.gov/grants/funding/phs398/label-bk.pdf has been modified to allow for this change. Please note this is in pdf format.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

Applications must be received by the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Research (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by a peer review group convened by CSR in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and may undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

REVIEW CRITERIA

The goals of NIH-supported research are to advance the understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of the application to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score.

(1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation: Does the project employ novel concepts, approaches, or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

Additional Review Criteria

Since the objective of this proposal is to invite research applications that may in whole or part consist of exploratory research rather than proof of a well-established idea, innovation will be given high priority in the review. Furthermore, there will be less emphasis on preliminary data with respect to highly innovative proposals. Although preliminary data should provide evidence that the applicant has the means and understanding to carry out the proposed studies, preliminary data does not necessarily have to provide a specific demonstration of the hypotheses to be tested.

The following evaluation will be presented in an administrative note in the Summary Statement, and will not factor into the numerical score:

- The adequacy of plans to make data available to other investigators in a timely fashion. What is the likelihood that the methods and materials generated in the project will be made widely available in a timely fashion to the scientific community, given the proposed plan to exercise (or not to exercise) intellectual property rights?

- The plan to share research resources and the plan to exercise (or not exercise) intellectual property rights regarding patentable research resources will be judged for appropriateness.

- The reasonableness of the proposed budget and duration in relation to the proposed research.

- The adequacy of the proposed protection for animals and the environment, to the extent they may be adversely affected by the project proposed in the application.

Schedule:

Letter of Intent Receipt Date: March 11, 2001
Application Receipt Date: April 11, 2001
Peer Review Date: June/July 2001
Council Review: September 2001
Earliest Anticipated Award Date: September 30, 2001

AWARD CRITERIA

Award criteria that will be used to make award decisions include: scientific merit as determined by peer review, adequacy of plans to make widely available to the research community all research resources developed during this project, adequacy of plans to exercise (or not exercise) intellectual property rights while permitting wide availability to the research community of patentable research resources developed during this project, availability of funds, and programmatic priorities.

INQUIRIES

Inquiries concerning this RFA are strongly encouraged. The opportunity to clarify issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.279 (NIDA), 93.173 (NIDCD), 93.867 (NEI), 93.242 (NIMH), 93.866 (NIA), 93.121 (NIDCR), 93.172 (NHGRI), 93.846 (NIAMS), 93.855 (NIAID), 93.853 (NINDS), and 93.847 (NIDDK). Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and are administered under NIH grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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